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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/083,233	10/24/2001	Walter J. Laird	1803-311-999	4738

7590 03/27/2003

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EXAMINER	
HASHEMI, SHAR S	

ART UNIT	PAPER NUMBER
1637	5

DATE MAILED: 03/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/083,233	Applicant(s) LAIRD ET AL.	
	Examiner Shar Hashemi	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 October 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☒ Claim(s) *1 and 11* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *"Notice to Comply..."* .

DETAILED ACTION

Specification

1. The use of the trademarks "ABI" (page 19, line 18) and "Dionex" (page 19, line 20) has been noted in this application. All trademarks should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

2. This application contains sequence disclosures (see page 23, lines 10-19) that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below or on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Sequence disclosures must have SEQ ID NO identifiers. Moreover, the primers disclosed on pages 26-33 and 35 must have SEQ ID NO identifiers.

APPLICANT IS GIVEN THE RESPONSE PERIOD SET FORTH IN THIS OFFICE ACTION IN WHICH COMPLY WITH THE SEQUENCE RULES, 37 CFR 1.821 – 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing petition accompanied by the extension fee under the provisions of 37 CFR 1.136. In no case may an applicant extend the

period for response beyond the six month statutory period. Applicant is requested to return a copy of the attached Notice to Comply with the response. The application is not in compliance for the reason(s) set forth on the attached Notice to Comply With the Sequence Rules or CRF Diskette Problem Report.

Claim Objections

3. Claims 1 and 11 are objected to because of the following informalities:

A) In claim 1, delete "a" before "least" on page 36, line 2, and insert "at".

B) In claim 11, delete "a" before "least" on page 37, line 9, and insert "at".

Appropriate correction is required.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-4, 6-8, 10-14, 16-18, and 20 rejected under 35 U.S.C. 103(a) as being unpatentable over Will (US 6,001,611 December 14, 1999) in view of Gold et al (US 2002/0172962 A1 November 21, 2002).

Will teaches a kit for carrying out a nucleic acid amplification reaction, wherein said kit comprises a pair of primers, wherein at least one primer of said pair contains a modified nucleotide within the three 3' terminal nucleotide positions. (see whole document, especially

col. 13, line 5 to col. 17, line 37). He mentions said modified nucleotide is at the 3' terminal position (col. 14, lines 24-67). Will discloses each primer of said primer pair independently contains a modified nucleotide within the three 3' terminal nucleotide positions (col. 14, line 40 to col. 17, line 37). He also reveals a method for amplifying a nucleic acid target sequence, wherein said method comprises carrying out a primer-based amplification reaction in a reaction mixture comprising a primer pair, wherein at least one primer of said pair contains a modified nucleotide within the three 3' terminal nucleotide positions (col. 12, line 45 to col. 17, line 37).

Will does not teach 2'-O-methyl nucleotide, 2'-fluoro-nucleotide, and 2'-amino nucleotide.

Gold et al teach modified nucleotides comprising 2'-O-methyl nucleotide, 2'-fluoro-nucleotide, and 2'-amino nucleotide (see whole document, especially page 37, claim 26).

One of ordinary skill at the time the invention was made would have been motivated to apply Gold et al's modified nucleotides to Will's kits and method for carrying out a nucleic acid amplification reaction utilizing primers that have been modified within the three 3' nucleotide positions in order to obtain a greater yield of the intended amplification product while reducing non-specific amplification. It would have been prima facie obvious to apply Gold et al's modified nucleotides to Will's kits and method for carrying out a nucleic acid amplification reaction utilizing primers that have been modified within the three 3' nucleotide positions in order to obtain a greater yield of the intended amplification product while reducing non-specific amplification.

6. Claims 5, 9, 15 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Will (US 6,001,611 December 14, 1999) in view of Gold et al (US 2002/0172962 A1 November 21, 2002) in further view of Reese (WO 00/56747 September 28, 2000).

The teachings and suggestions of Will and Gold et al have been described previously.

Will does not teach arabinose nucleotide.

Reese teaches arabinose nucleotide (see whole document, especially lines 4-29).

One of ordinary skill at the time the invention was made would have been motivated to apply Reese's modified arabinose nucleotides to Will's and Gold et al's combined kit and method for carrying out a nucleic acid amplification reaction because amplification reactions that utilize modified primers result in a greater yield of the intended amplification product while reducing non-specific amplification. It would have been prima facie obvious to apply Reese's modified arabinose nucleotides to Will's and Gold et al's combined kit and method for carrying out a nucleic acid amplification reaction because amplification reactions that utilize modified primers result in a greater yield of the intended amplification product while reducing non-specific amplification.

SUMMARY

7. No claims allowed.

CONCLUSION

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shar Hashemi whose telephone number is (703) 305-4840 and whose e-mail address is shar.hashemi@uspto.gov. However, the Office cannot guarantee

security through the e-mail system nor should official papers be transmitted through this route. The examiner is on flex-time schedule and can be best reached on weekdays from 7:00 a.m. to 3:30 p.m. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119.

Any inquiry of a general nature, matching or filed papers or relating to the status of this application or proceeding should be directed to the Tracey Johnson for Art Unit 1637 whose telephone number is (703) 305-2982.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Center numbers for Group 1600 are Voice (703) 308-1235 and Before Final FAX (703) 872-9306 or After Final FAX (703) 308-9307.

March 18, 2003

GARY BENZION, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NUMBER	FILING/RECEIPT DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
10/083,233	10/24/2001	Laird et al	1803-311-999

DATE MAILED:

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 CFR 1.821–1.825 for the following reason(s):

☑ 1. This application fails to comply with the requirements of 37 CFR 1.821–1.825.

☑ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 CFR 1.821(c).

☑ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 CFR 1.821(e).

A copy of the "Sequence Listing" in computer readable form has been submitted. The content of the computer readable form, however, does not comply with the requirements of 37 CFR 1.822 and/or 1.832, as indicated on the attached marked–up copy of the "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A substitute computer readable form must be submitted as required by 37 CFR 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 CFR 1.821(e).

☐ 7. OTHER: _____

APPLICANT MUST PROVIDE:

☑ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing."

☑ An initial or substitute paper copy of the "Sequence Listing," as well as an amendment directing its entry into the specification.

☑ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b) or 1.825(d).

FOR QUESTIONS REGARDING COMPLIANCE WITH THESE REQUIREMENTS, PLEASE CONTACT:

☑ For Rules Interpretation, call (703) 308–1123.

☐ For CRF submission help, call (703) 308–4212.

☑ For PatentIn software help, call (703) 308–6856.

Customer Service Center
Initial Patent Examination Division (703) 308–1202

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